DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 15, 2015

Chang Gung Medical Technology Co., Ltd.
Mr. Chao-Chun Chiu
Manager
11F., No. 201-4, DungHua North Rd., Song Shan District
Taipei City, Taiwan 10508
REPUBLIC OF CHINA

Re: K142751
Trade/Device Name: Chang Gung "ComMed" Series Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE, NHA
Dated: May 11, 2015
Received: May 13, 2015

Dear Mr. Chiu:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142751

Device Name
Chang Gung "ComMed" Series Dental Implant System

Indications for Use *(Describe)*
"ComMed" Series Dental Implant System is intended for surgical placement in the maxilla or mandible to provide for prosthetic attachment to restore a patient's chewing function. "ComMed" Series Dental Implants are intended only for delayed loading.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Chang Gung Medical Technology Co., Ltd.

Chapter 4 510(k) Summary

Type of Submission	Original Application - Traditional 510(k)
Device Name	Chang Gung "ComMed" Series Dental Implant System
Validated Date	2015.06.12
Version	1.4

11F., No. 201-4, Dunghua N. Rd., Song Shan Dist. Taipei City, TAIWAN 10508

Tel: +886 2 8712 2948 Fax: +886 2 2514 0620

4.1 Applicant Information

Type of Submission	Original Application- Traditional 510(k)
Applicant Name	Chang Gung Medical Technology Co., Ltd.
Address	Office：Chang Gung Medical Technology Co., Ltd. 11F., No. 201-4, Dunghua N. Rd., Song Shan Dist. Taipei City, TAIWAN 10508 Factory：Chang Gung Medical Technology Co., Ltd. Linkou Factory 2F., No. 118, Nanlin Rd., Taishan Dist., New Taipei City 24352, Taiwan (R.O.C.)
Phone	+886 2 8712 2948
Fax	+886 2 2514 0620
Contact Person	Heng-Liang Liu
Contact Title	Project Manager
Contact E-mail	hlliu@cgmc.com.tw

4.2 Device Description

Common Name	Dental Implant
Trade Name	Chang Gung "ComMed" Series Dental Implant System
Classification Name	Implant, Endosseous, Root-form
Regulation Number	872.3640
Product Code	DZE, NHA
Device Class	Class II

4.3 Technological Characteristics of Device

Product Name	Chang Gung "ComMed" Series Dental Implant System
Regulation Number	872.3640
Product Code	DZE, NHA
Intended Use	"ComMed" Series Dental Implant System is intended for surgical placement in the maxilla or mandible to provide means for prosthetic attachment to restore a patient’ s chewing function. "ComMed" Series Dental Implants are intended only for delayed loading.
Material	Implant: Grade 4 Pure Titanium Abutment: Ti6Al4V
Connection	Internal Hex with Morse Taper 8°
Platform Switching	YES
Fine thread in Neck	YES
Diameter (mm)	3.5, 4.0, 4.5, 5.0, 5.5, 6.0
Length (mm)	10, 11, 12, 13, 14, 15,16
Angle Abutment	YES (15°)
Surface Treatment	Blasted with Aluminum Oxide and Acid Etched.
Anodized Treatment	YES
Sterilization method	Implant：Gamma irradiation Abutment：Moist heat sterilization before use by clinicians.

Components

Name	Function	Accessories
Standard Implant (Fixture)	A cylindrical and tapered post that serves as a substitute for the tooth root.	Cover Screw Mount Mount Screw
Healing Abutment	Attached to the fixture for gingival forming.	N/A
Standard Abutment	A connector built into the top of the fixture to straightly attach the implant to the replacement tooth.	Abutment Screw
Angle Abutment	A connector built into the top of the fixture to obliquely attach the implant to the replacement tooth.	Abutment Screw
Accessories		
Cover Screw	A screw placed on the superior part of a fixture during osseointegration period. The Cover Screw size depends on the corresponding Standard Implant.	N/A
Mount	A temporary part to connect fixture to driver for placement. The Mount size depends on the corresponding Standard Implant.	N/A
Mount Screw	Connection implant with mount. The Mount Screw size depends on the corresponding Standard Implant.	N/A
Abutment Screw	Connection implant with standard abutment or angle abutment. The Abutment Screw size depends on the corresponding Abutment.	N/A

Specification

- Standard Implant：

Ø 3.5 Ø 4.0 Ø 4.5 Ø 5.0 Ø 5.5 Ø 6.0

Model Type	Model No.	Ø /L(mm)	Model Type	Model No.	Ø /L(mm)	Model Type	Model No.	Ø /L(mm)
Standard Implant	UTAA3510	Ø 3.5 / L 10.0	Standard Implant	UTAA4510	Ø 4.5 / L 10.0	Standard Implant	UTAA5510	Ø 5.5 / L 10.0
	UTAA3511	Ø 3.5 / L 11.0		UTAA4511	Ø 4.5 / L 11.0		UTAA5511	Ø 5.5 / L 11.0
	UTAA3512	Ø 3.5 / L 12.0		UTAA4512	Ø 4.5 / L 12.0		UTAA5512	Ø 5.5 / L 12.0
	UTAA3513	Ø 3.5 / L 13.0		UTAA4513	Ø 4.5 / L 13.0		UTAA5513	Ø 5.5 / L 13.0
	UTAA3514	Ø 3.5 / L 14.0		UTAA4514	Ø 4.5 / L 14.0		UTAA5514	Ø 5.5 / L 14.0
	UTAA3515	Ø 3.5 / L 15.0		UTAA4515	Ø 4.5 / L 15.0		UTAA5515	Ø 5.5 / L 15.0
	UTAA3516	Ø 3.5 / L 16.0		UTAA4516	Ø 4.5 / L 16.0		UTAA5516	Ø 5.5 / L 16.0
	UTAA4010	Ø 4.0 / L 10.0		UTAA5010	Ø 5.0 / L 10.0		UTAA6010	Ø 6.0 / L 10.0
	UTAA4011	Ø 4.0 / L 11.0		UTAA5011	Ø 5.0 / L 11.0		UTAA6011	Ø 6.0 / L 11.0
	UTAA4012	Ø 4.0 / L 12.0		UTAA5012	Ø 5.0 / L 12.0		UTAA6012	Ø 6.0 / L 12.0
	UTAA4013	Ø 4.0 / L 13.0		UTAA5013	Ø 5.0 / L 13.0		UTAA6013	Ø 6.0 / L 13.0
	UTAA4014	Ø 4.0 / L 14.0		UTAA5014	Ø 5.0 / L 14.0		UTAA6014	Ø 6.0 / L 14.0
	UTAA4015	Ø 4.0 / L 15.0		UTAA5015	Ø 5.0 / L 15.0		UTAA6015	Ø 6.0 / L 15.0
	UTAA4016	Ø 4.0 / L 16.0		UTAA5016	Ø 5.0 / L 16.0		UTAA6016	Ø 6.0 / L 16.0

- **Healing Abutment：**

Ø 3.5 Ø 4.0 Ø 4.5 Ø 5.0 Ø 5.5 Ø 6.0

Model Type	Model No.	Specification	Model Type	Model No.	Specification
Healing Abutment	UTAB3501	Ø 3.5mm / GH 1	Healing Abutment	UTAB5001	Ø 5.0mm / GH 1
	UTAB3503	Ø 3.5mm / GH 3		UTAB5003	Ø 5.0mm / GH 3
	UTAB3505	Ø 3.5mm / GH 5		UTAB5005	Ø 5.0mm / GH 5
	UTAB4001	Ø 4.0mm / GH 1		UTAB5501	Ø 5.5mm / GH 1
	UTAB4003	Ø 4.0mm / GH 3		UTAB5503	Ø 5.5mm / GH 3
	UTAB4005	Ø 4.0mm / GH 5		UTAB5505	Ø 5.5mm / GH 5
	UTAB4501	Ø 4.5mm / GH 1		UTAB6001	Ø 6.0mm / GH 1
	UTAB4503	Ø 4.5mm / GH 3		UTAB6003	Ø 6.0mm / GH 3
	UTAB4505	Ø 4.5mm / GH 5		UTAB6005	Ø 6.0mm / GH 5

- **Standard Abutment :**

Ø 3.5 Ø 4.0 Ø 4.5 Ø 5.0 Ø 5.5 Ø 6.0

Model Type	Model No.	Specification	Model Type	Model No.	Specification
Standard Abutment	UTBA3501	Ø 3.5mm / GH 1	Standard Abutment	UTBA5001	Ø 5.0mm / GH 1
	UTBA3503	Ø 3.5mm / GH 3		UTBA5003	Ø 5.0mm / GH 3
	UTBA3505	Ø 3.5mm / GH 5		UTBA5005	Ø 5.0mm / GH 5
	UTBA4001	Ø 4.0mm / GH 1		UTBA5501	Ø 5.5mm / GH 1
	UTBA4003	Ø 4.0mm / GH 3		UTBA5503	Ø 5.5mm / GH 3
	UTBA4005	Ø 4.0mm / GH 5		UTBA5505	Ø 5.5mm / GH 5
	UTBA4501	Ø 4.5mm / GH 1		UTBA6001	Ø 6.0mm / GH 1
	UTBA4503	Ø 4.5mm / GH 3		UTBA6003	Ø 6.0mm / GH 3
	UTBA4505	Ø 4.5mm / GH 5		UTBA6005	Ø 6.0mm / GH 5

- Angle Abutment：

■ Ø 3.5 ■ Ø 4.0 ■ Ø 4.5 ■ Ø 5.0 ■ Ø 5.5 ■ Ø 6.0

Model Type	Model No.	Specification	Model Type	Model No.	Specification
Angle Abutment	UTBB3501	Ø 3.5mm / 15°/ GH 1	Angle Abutment	UTBB5001	Ø 5.0mm / 15°/ GH 1
	UTBB3503	Ø 3.5mm / 15°/ GH 3		UTBB5003	Ø 5.0mm / 15°/ GH 3
	UTBB3505	Ø 3.5mm / 15°/ GH 5		UTBB5005	Ø 5.0mm / 15°/ GH 5
	UTBB4001	Ø 4.0mm / 15°/ GH 1		UTBB5501	Ø 5.5mm / 15°/ GH 1
	UTBB4003	Ø 4.0mm / 15°/ GH 3		UTBB5503	Ø 5.5mm / 15°/ GH 3
	UTBB4005	Ø 4.0mm / 15°/ GH 5		UTBB5505	Ø 5.5mm / 15°/ GH 5
	UTBB4501	Ø 4.5mm / 15°/ GH 1		UTBB6001	Ø 6.0mm / 15°/ GH 1
	UTBB4503	Ø 4.5mm / 15°/ GH 3		UTBB5001	Ø 6.0mm / 15°/ GH 1
	UTBB4505	Ø 4.5mm / 15°/ GH 5		UTBB5003	Ø 6.0mm / 15°/ GH 3

4.4 Predicate and Reference Devices

	Subject Device	Predicate device	Reference device #1	Reference device #2
510(k) Number	-	K033984	K073075	K040807
Indication for use	"ComMed" Series Dental Implant System is intended for surgical placement in the maxilla or mandible to provide means for prosthetic attachment to restore a patient' s chewing function. "ComMed" Series Dental Implants are intended only for delayed loading.	The ITI Dental System implants are for single-stage or two-stage surgical procedures. The implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved and with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, 4 or more implants must be used in immediately	The FRIADENT Implant systems are for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The FRIADENT Implant Systems are intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be splinted with a bar.	The MIS Dental Implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function.

		loaded cases.		
Trade name	Chang Gung "ComMed" Series Dental Implant System	STRAUMANN DENTAL IMPLANT SYSTEM	FRIADENT Implant Systems – XiVE® S Plus Dental Implant System	MIS DENTAL IMPLANT SYSTEM
Material	Implant: Grade 4 Pure Titanium Abutment: Ti-6Al-4V	Implant: Grade 4 Pure Titanium Abutment: Grade 4 Pure Titanium	Implant: Grade 2 Pure Titanium Abutment: Ti-6Al-4V / Grade 2 Pure Titanium	Implant: Grade 4 Pure Titanium Abutment: Ti-6Al-4V
Connection type	Internal hex with Morse taper 8°	Internal hex with Morse taper	Internal hex	Internal hex with Morse taper, internal octa with Morse taper
Platform switching	Yes	Yes	No	No
Micro-thread at implant neck	Yes	No	No	Yes
Diameter (mm)	3.5, 4.0, 4.5, 5.0, 5.5, 6.0	3.3~4.8	3.0~5.5	3.3~6.0
Length (mm)	10, 11, 12, 13, 14, 15, 16	8~14	8~18	6~16
Angle abutment	Yes (15°)	Yes (15°)	Yes (15°)	Yes (15°)
Surface modification	Blasted with aluminum oxide and acid etched	Blasted with aluminum oxide and acid etched	Blasted with aluminum oxide and acid etched	Blasted with aluminum oxide and acid etched
Anodizing	Yes	Yes	Yes	Yes
Sterilization method	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation

4.5 Substantial Equivalence

Substantially equivalence is claimed to the following legally marketed predicate device: STRAUMANN DENTAL IMPLANT SYSTEM (K033984) and reference device: FRIADENT Implant Systems – XiVE® S Plus Dental Implant System (K073075) and MIS DENTAL IMPLANT SYSTEM (K040807). The above comparison table lists the primary technological characteristics and specifications that are pertinent to Dental Implant Systems. Based on the comparison analysis, the proposed device is identical to the predicate and reference devices in terms of intended use, materials, surface treatment, sterilization method, and comparable technological characteristics and general design features.

All minor differences in design features (connection type, platform switching and micro-thread at implant neck) exist between the subject and the predicate and reference devices have been evaluated per the testing described in section 4.6 (non-clinical testing) following the recommendations in the "Class II Special Controls Guidance Document: Root-form Endosseous Dental Implant and Endosseous Dental Implant Abutments" . The results of non-clinical testing support that these minor differences do not raise any new questions of safety and effectiveness.

It is concluded that the Chang Gung "ComMed" Series Dental Implant System is substantially equivalent to the predicate and reference devices.

4.6 Non-clinical Testing

Performance testing was conducted to support the substantial equivalence of the subject device. This testing included Static and Dynamic fatigue loading, Biocompatibility, Packaging Shelf Life Validation and Sterilization Validation (Table 1).

Table 1. Tests and relevant standards

	Device	Test	Relevant standard
Biocompatibility	Implant	In vitro cytotoxicity study	ISO 10993-5
		Intracutaneous reactivity study	ISO 10993-10
		Skin sensitization study	ISO 10993-10
		Acute systemic toxicity	ISO 10993-11
		Pyrogenicity study	ISO 10993-11
		14-day repeated dose systemic toxicity study	ISO 10993-11
		In vitro haemolysis study	ISO 10993-4
		In vitro bacterial reverse mutation (AMES) study	ISO 10993-3
		In vitro chromosome aberration study	ISO 10993-3
		In vitro mammalian cell gene mutation study	ISO 10993-3
		Bone formation and histological study	ISO 10993-6
	Abutment	In vitro cytotoxicity study	ISO 10993-5
		Intracutaneous reactivity study	ISO 10993-10
		Skin sensitization study	ISO 10993-10

Static and dynamic fatigue loading	Implant and standard abutment	Static and dynamic fatigue test	ISO 14801
	Implant and angle abutment	Static and dynamic fatigue test	ISO 14801
Sterilization validation	Implant	Sterilization validation of Gamma irradiation	ISO 11737-1 ISO 11737-2
	Abutment	Moist heat validation- microbiological performance qualification	ISO 11737-1 ISO 11737-2 ISO 17665-1
Packaging shelf life validation	Implant	Burst and creep tests	ASTM F1140
		Dye penetration test	ASTM F1929
		Seal peel test	ASTM F88/F88M
		Microbial ranking test	ASTM F1608
		Burst, creep, dye penetration, seal peel, and microbial ranking tests after 2 years accelerated aging	ASTM F1980 ASTM F1140 ASTM F1929 ASTM F88/F88M ASTM F1608
		Burst, creep, dye penetration, seal peel, and microbial ranking tests after 3 years accelerated aging	ASTM F1980 ASTM F1140 ASTM F1929 ASTM F88/F88M ASTM F1608
		Burst, creep, dye penetration, seal peel, and microbial ranking tests after 5 years accelerated aging	ASTM F1980 ASTM F1140 ASTM F1929 ASTM F88/F88M ASTM F1608

4.7 Conclusion

This submission is seeking marketing clearance for the Chang Gung "ComMed" Series Dental Implant System which includes threaded root-form endosseous dental implants as well as dental implant abutments. These devices have been evaluated using non-clinical performance and bench testing. This testing included static and dynamic mechanical loading, biocompatibility testing, sterilization validation, and packaging life validation. The technological characteristics of this device system do not raise different questions of safety and effectiveness. The information included in this submission supports the substantial equivalence of the Chang Gung "ComMed" Series Dental Implant System to the identified predicate and reference devices for its intended use.